November 11, 2022

ImSonic Medical China, INC.
℅ Xiaohui Hao
CEO
No. 168 Yuanfeng Road
Kunshan, Jiangsu Province 215300
CHINA

Re: K220983
Trade/Device Name: ImSonic TR-1 Ultrasonic Pulsed Doppler Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 11, 2022
Received: October 12, 2022

Dear Xiaohui Hao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220983

Device Name
ImSonic TR-1 Ultrasonic Pulsed Doppler Imaging System

Indications for Use *(Describe)*
ImSonic TR-1 Ultrasonic pulsed doppler imaging system is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. The system is intended to be used in a hospital or clinic setting. Specific clinical applications and exam types include:

Fetal/obstetric
Gynecological /Pelvic
Abdominal
Renal
Cardiac
Pediatric
Small organ (thyroid, breast, testes, etc.)
Musculoskeletal (conventional & superficial)
Peripheral vascular
Ophthalmic

Modes of operation include B, M, PWD(PW), Color Doppler (C), B+M, B+Color Doppler, B+PWD, Biopsy, Harmonics (Tissue), Contrast Imaging (CPS), Steered Spatial Compounding (SSC).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

510(k) Summary

ImSonic TR-1

K220983

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

Date Prepared: 10/11/22

Manufacturer: ImSonic Medical China, INC.
168 Yuanfeng Road, Kunshan City, Jiangsu Province, China
Establishment Registration Number: TBD

Primary Contact Person:
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CEO
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Device:	Common/usual name:	Diagnostic Ultrasound System and Transducers
	Proprietary name:	ImSonic TR-1 Ultrasonic Pulsed Doppler Imaging System
	Classification Regulation:	21CFR §892.1550
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	IYN (System, Imaging, Pulsed Doppler, Ultrasonic)
	Secondary Product Code:	ITX (Transducer, Ultrasonic, Diagnostic)
		IYO (Ultrasonic Pulsed Echo Imaging System)
Primary Predicate Device:	Trade Name:	FUJIFILM SonoSite X-Porte Ultrasound System
	Manufacturer:	FUJIFILM Sonosite, Inc.
	510(k) Clearance:	K152209 (08/19/2015)
Reference device:	Trade Name:	CX50 Diagnostic Ultrasound System
	Manufacturer:	Philips Ultrasound, Inc.
	510(k) Clearance:	K162329 (09/14/2016)

Device description: The ImSonic TR-1 is a general purpose, mobile Ultrasonic Pulsed Doppler Imaging System. The function is to acquire ultrasound data and to display in various modes of operation. The device consists of two parts: the system console and the transducers. The system console contains the user interface, a display, a touch screen, a control panel, system electronics and optional peripherals (barcode scanner, printer). The removable transducers are connected to the system using a standard technology, multi-pin connectors.

Indications for Use: The ImSonic TR-1 is intended to be used by qualified physicians and healthcare professionals for the evaluation or fluid flow analysis of the human body, contrast-enhanced sonography and guidance of puncture and biopsy. The system is intended to be used in a hospital or clinic setting. Specific clinical applications and exam types include:
Fetal/obstetric
Gynecological /Pelvic
Abdominal
Renal
Cardiac
Pediatric
Small organ (thyroid, breast, testes, etc.)
Musculoskeletal (conventional & superficial)
Peripheral vascular
Ophthalmic

Modes of operation include B, M, PWD(PW), Color Doppler (C), B+M, B+Color Doppler, B+PWD, Biopsy, Harmonics (Tissue), Contrast Imaging (CPS), Steered Spatial Compounding (SSC).

Technological characteristics: The ImSonic TR-1 Diagnostic Ultrasound System and the predicate, SonoSite X-Pore Ultrasound System cleared in K152209, are Track 3 systems and employ similar fundamental scientific technology. They are similar in materials, type of transducers, optimization, accessories and imaging modes. The primary differences between the ImSonic Diagnostic Ultrasound Systems and the predicate device is the additional transducer.

Table 2. Comparison of ImSonic Features to the Predicate Device

Standard Feature	**ImSonic TR-1 (proposed device)**	**SonoSite X-Porte Ultrasound System (K152209) (Predicate Device)**
Intended Use	The ImSonic TR-1 is intended to be used by qualified physicians and healthcare professionals for the evaluation or fluid flow analysis of the human body, contrast-enhanced sonography and guidance in biopsy. The system is intended to be used in a	Diagnostic ultrasound imaging or fluid flow analysis of the human body. The system is intended to be used in a hospital or clinic setting.

	hospital or clinic setting.	
Indications for Use	Fetal/obstetrics Gynecological /Pelvic Abdominal Renal Cardiac Pediatric Small organ (thyroid, breast, testes, etc.) Musculoskeletal (conventional & superficial) Peripheral vascular Ophthalmic	Ophthalmic Fetal-OB/GYN Abdominal Intra-operative (abdominal organs and vascular) Pediatric Small Organ (breast, thyroid, testicle, prostate) Neonatal Cephalic Adult Cephalic Trans-Vaginal Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac Adult Cardiac Pediatric Trans-esophageal (cardiac) Peripheral Vessel Needle guidance
Transducer Types	Linear Array Curved Linear Array Phased Array	Linear Array Curved Linear Array Intracavitary Phased Array
Transducer Frequency	1.5 – 20.0MHz	1.0 – 15.0 MHz

Acoustic Output Display & FDA Limits	ISTPA.3 ≤720 (mW/cm2) TI≤ 6.0 MI≤1.9 Display Feature for Higher Outputs MI Output Display TI Output Display	ISTPA.3 ≤720 (mW/cm2) TI≤ 4.0 MI≤1.9 Display Feature for Higher Outputs MI Output Display TI Output Display
Modes of Operation	B-mode Grayscale Imaging Tissue Harmonic Imaging M mode (including Simultaneous M mode) Combination Modes PW mode (Pulsed Wave Doppler) C mode(Color Doppler) CPS（Contrast Pulse Sequence）mode imaging SSC (B Steer Spatial Compounding) Biopsy	B- mode Grayscale Imaging Tissue Harmonic Imaging M-mode Simultaneous M-Mode Color Power Doppler Zoom Combination Modes Pulsed Wave (PW) Doppler Continuous Wave (CW) Doppler SonoHD2 Noise Reduction SonoMB/MBe Image Compounding Steered CW Doppler Velocity Color Doppler Tissue Doppler Imaging (TDI)

PW Doppler	Available	Available
CW Doppler	Not available	Available
Velocity Color Doppler	Available	Available
Elastography (Strain), and Strain Rate Imaging	Not available	Not available
CPS	Available for contrast imaging	Not available
ECG Feature	Not available	3-lead ECG input
DICOM	DICOM 3.0	DICOM 3.0
IMT Measurement	Not available	Not available
Patient Contact Materials	Transducers: Plastic housing:PA757 Bonding material:KE45 C5-2, PA5-2 and LN14-4 Lens material: RTV630 L13-3 Lens material: RTV615	Transducers: Acrylonitrile-butadien-styrene (ABS) Cycoloy Dow Medical Adhesive, Type A Epoxy paste adhesive Polyethylene (PE) Ionomer Polyetheretherketone (PEEK) Polysulfone UDEL P1700 Polyurethane Poly-Vinyl-Chloride (PVC) Silicone RTV Adhesive Silicone

		Rubber Urethane Needle Guides: Acetal copolymer Acrylonitrile-butadien-styrene (ABS)
System Characteristics	ImSonic TR-1（stand configuration）： Beam former 128/128 using SA (configurable)： Display: 23.8″ TFT Liquid Crystal Display module with WLED Backlight unit and 30 pins 2ch-LVDS interface. 1920 x 1080 Full HD mode and can display up to 16.7M colors. Touchscreen: 13.3″Capacitive touch screen interface Physical Dimensions: Height: 1,470 – 1,830mm (with Display) Width: 774mm Depth: 576mm Weight of Main system:60Kg (with monitor) Main Power box with battery: 6Kg Measurement Packages: Abdomen, Aorta, Biliary, Bladder, Cardiac, Lt. Kidney, Rt. Kidney, MSK, Obstetrical, Left Ovary, Right Ovary, Pelvic, and	X-Porte (stand configuration): Beam former 128/128 using SA (configurable) 12.1” Capacitive touch screen interface 19” LED LCD HD monitor 256 gray shades on LED LCD 6 USB 2.0 ports Stand Base Dimensions: 26.4” L x 21.2” W Stand Height (max): 64” (monitor up) Stand Height (min): 42.2” (monitor down) Weight: 149.35 lbs (fully configured w/ 3 transducers System operates via battery or AC power Battery life: 1 hour operational - 3 days idle Input: 100 – 240 VAC, 50/60 Hz Output 1: 24VDC output, 275 W max Output 2: 100-240VAC,

	Testicular. Trackball operation of multiple cursors Distance, Area, Volume and Angle measurements in all imaging modes, Heart Rate (HR) and Time measurements in PW mode and M mode, and Velocity measurements in PW mode. Support to use annotation tools: Text, arrow, body mark 1 USB 3.0ports 1 DVI-D port Ethernet port: 10/100/1000 Mbps Transducers System operates via battery or AC power Battery life: 2.0 hour operational Input: AC100 – 240 V options, 50/60 Hz Internal power:14.4V/30Ah	50-60 Hz (AC Printer) Various obstetrical, cardiac, volume, M-mode, PW and CW Doppler measurement and calculation packages ECG acquisition and display capabilities CW/PW Doppler Audio Spectral Doppler Audio and image storage on removable media Measurement on Recalled Images. Wireless 802.11 (a/b/g/n) support for image transfer X-Porte (desktop configuration): Same software features/capabilities as the stand configuration. Does not have the stand, touch panel interface, DVR, and mobile power unit. Weight: 32.80 lbs (w/ 1 transducer) AC power only. 100 – 240V options, 50/60 Hz
510(k) Track	Track 3	Track 3

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the ImSonic TR-1 Diagnostic Ultrasound System and demonstrates compliance with the following FDA recognized consensus standards:

- ANSI/AAMI ES 60601-1:2005/(R)2012 +A1:2012+C1:2009/(R) 2012+A2:2010/(R)2012: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014

- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability, 2010+A1:2013
- IEC 62304: Medical device software – Software life cycle processes, 2015
- ISO 14971: Medical devices - Application of risk management to medical devices, 2019
- NEMA UD 2-2004: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA PS 3.15: Digital Imaging and Communications in Medicine (DICOM), Part 15: Security and System Management Profiles, 2021e

The ImSonic TR-1 Diagnostic Ultrasound System also complies with the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff –Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (June 27, 2019)

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures. Non-Clinical validation testing covered the intended use as well as usability testing with representative intended users.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the ImSonic Diagnostic Ultrasound System:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA ultrasound guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

The system acoustic output limits are:

- Ispta 3$\leq$ 720 MW/cm^2
- MI $\leq$ 1.9
- TI $\leq$ 6.0

Therefore, ImSonic TR-1 Diagnostic Ultrasound System is substantially equivalent to the predicate FUJIFILM SonoSite X-Porte Ultrasound System in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The ImSonic TR-1 Diagnostic Ultrasound System and its transducers did not require clinical data to support the determination of substantial equivalence.

Substantial Equivalence Conclusion:

In conclusion, the predicate device and subject device have same intended use and similar technological features. The nonclinical tests conducted, demonstrate that the ImSonic TR-1 meets applicable requirements and standards for safety and effectiveness of the device for its intended use. Therefore, the subject device is as safe

and effective and substantially equivalent to the primary predicate device that is currently marketed for the same intended use.